

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION	)	
and GENEVANT SCIENCES GmbH,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 22-252 (JDW)
	)	
MODERNA, INC. and MODERNATX, INC.	)	
	)	
Defendants.	)	
<hr/>		
MODERNA, INC. and MODERNATX, INC.,	)	
	)	
Counterclaim-Plaintiffs,	)	
	)	
v.	)	
	)	
ARBUTUS BIOPHARMA CORPORATION	)	
and GENEVANT SCIENCES GmbH,	)	
	)	
Counterclaim-Defendants.	)	

**MODERNA’S REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE  
DR. MITCHELL’S OPINIONS FOR PURPOSES OF SUMMARY JUDGMENT**

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Pursuant to paragraph II.B.2 of this Court’s Policies and Procedures and D. Del. LR 7.1.2 and 7.1.3, Moderna respectfully submits this Reply to Plaintiffs’ Opposition to Moderna’s Motion to Exclude Certain Testimony of Mitchell (D.I. 611) (“Plaintiffs’ MTE Opposition”).<sup>1</sup>

## I. INTRODUCTION

Plaintiffs scrambled at the last minute to rely on the opinions from Dr. Mitchell’s report in support of a late-breaking fraud theory to counter Moderna’s § 1498 defense—a theory Plaintiffs never disclosed during years of litigation. Worse yet, in the short time since Plaintiffs belatedly asserted that theory, it has been a moving target. In their opposition to Moderna’s motion for summary judgment, the supposed fraud concerned *literal* infringement. When Moderna demolished that assertion in reply, Plaintiffs shifted to an *entirely new* theory in sur-reply based on the doctrine of equivalents (“DOE”), all in an effort to gin up a factual dispute that would force a jury, rather than a court, to resolve Moderna’s § 1498 defense, likely for the first time in the statute’s 75-year history. That is precisely the opposite of what Plaintiffs told Judge Goldberg just a few months ago, long after fact discovery closed. D.I. 484 (June 12, 2025 Hr’g Tr.) at 18:7–19 (“To be perfectly candid, we expect that the Court will resolve [the § 1498] issue in our favor o[r] Moderna’s favor before trial”).

Plaintiffs’ gamesmanship has deprived Moderna of fair notice and underscores why Dr. Mitchell’s testimony should be excluded. At a minimum, the Court should exclude the opinions

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<sup>1</sup> This Court’s Policies and Procedures and the Local Rules do not require leave of Court to submit a reply brief. But should Plaintiffs claim otherwise, Moderna respectfully submits that leave is warranted to address the new and undisclosed arguments in Plaintiffs’ MTE Opposition, just as Plaintiffs had ample opportunity to file a reply brief addressing arguments in Moderna’s opposition to Plaintiffs’ motion to exclude. *See, e.g., EMC Corp. v. Pure Storage, Inc.*, 154 F. Supp. 3d 81, 103 (D. Del. 2016) (granting leave to file sur-reply that responded to new arguments raised in reply brief); *St. Clair Intellectual Prop. Consultants, Inc. v. Samsung Elecs. Co.*, 291 F.R.D. 75, 80 (D. Del. 2013) (granting leave to file sur-reply after concluding that the “sur-reply will allow the Court to more fully and fairly evaluate [the pending motion]”).

from Dr. Mitchell regarding DOE, which were raised for the first time in Plaintiffs' summary judgment sur-reply.

## II. ARGUMENT

### A. Contrary to Plaintiffs' Belated Fraud Theory, Moderna's Motion to Exclude Dr. Mitchell's Testimony Is Timely and Properly Raised

Plaintiffs suggest that Moderna's motion to exclude is procedurally improper because it was not filed at the time Moderna moved for summary judgment. D.I. 610 (Plaintiffs' Sur-Reply SJ Br.) at 1–2. That makes no sense given the context: Dr. Mitchell is an infringement expert, and the parties are not seeking summary judgment on infringement. During discovery, Plaintiffs did not disclose that they were relying on Dr. Mitchell in relation to § 1498, nor in connection with summary judgment. The first time Plaintiffs raised Dr. Mitchell in relation to § 1498 was when they cited his report in their opposition to Moderna's summary judgment motion on § 1498. D.I. 564 at 14–16. Because Moderna does not have a crystal ball, its only recourse was to move to exclude Dr. Mitchell promptly thereafter, which is precisely what Moderna did. D.I. 596 at 16–20. In short, Moderna's motion to exclude was timely raised. And to avoid further adding to the docket with a *separate* motion to exclude, Moderna more efficiently incorporated its motion into its existing expert-related briefing.

That sharply contrasts with Plaintiffs' belated (and constantly evolving) disclosure of their fraud theory. The parties litigated Moderna's § 1498 defense for years, yet not once did Plaintiffs disclose that they intended to oppose that defense by arguing that Moderna fraudulently induced the Government to enter the C-100 Contract, let alone that they were relying on infringement evidence and expert opinion to do so. *See* D.I. 600-31, Ex. 119 (ROG 14 Resp.) at 5 (stating only that “to the extent that [the C-100 Contract and the Government's Statement of Interest] point toward the Government's authorization and consent, they are undermined to the extent that

Moderna made any misrepresentation to the Government about the scope of Moderna's infringement of Plaintiffs' patents" (emphasis added), while failing to actually identify or point to any alleged misrepresentation or "fraud," or cite any evidence or infringement allegation). And while Plaintiffs contend that their vague interrogatory responses were clear enough to surface this issue, they ignore their later supplemental response drafted deposing Moderna's corporate representative (Hamilton Bennett) in May 2024 on the negotiation of the C-100 Contract and the inclusion of the FAR 52.227-1 clauses, which constitute the U.S. Government's authorization and consent under § 1498(a). Rather than expand on alleged "misrepresentations" in their supplemental response, Plaintiffs *disavowed* that theory by stating that Moderna did not "negotiate for the inclusion of FAR Clause 52.227-1 or Alt-1." D.I. 600-31, Ex. 119 (ROG 14 1st Supp. Resp., dated June 7, 2024) at 12, 17 (citing Bennett 5/20/2024 Tr. at 265:15–268:7).

If Plaintiffs had truly uncovered a fraud during discovery that needed to go to a jury, they certainly would have raised it during Judge Goldberg's pre-summary judgment procedures, including in the letters filed on the parties' proposed motions or during the hearings discussing those letters. *See* D.I. 446, 456, 462, 464, 466, 484. At a minimum, Plaintiffs certainly would *not* have suggested to the Court that § 1498 was "amenable to summary judgment" on cross-motions just months ago. D.I. 466 at 2; *see also* D.I. 484 (June 12, 2025 Hr'g Tr.) at 18:7–19 (Plaintiffs' counsel representing to the Court that, "both sides have agreed that they're going to move for summary judgment on that issue. To be perfectly candid, we expect that the Court will resolve that issue in our favor o[r] Moderna's favor before trial" and that "Your Honor likely will say that Moderna wins on 1498 or we win on 1498").

Compounding the prejudice to Moderna caused by Plaintiffs' failure to disclose this fraud theory and their reliance on Dr. Mitchell, Plaintiffs' MTE Opposition and SJ Sur-Reply completely

alter the basis for this theory. When Plaintiffs raised their undisclosed fraud theory in opposition to Moderna's motion for summary judgment, they based their position on Dr. Mitchell's opinions on literal infringement. D.I. 564 (Plaintiffs' Opposition SJ Br.) at 14 (citing "Ex. 48 (Mitchell) ¶¶ 453–476, 497–502, 609–621," which correspond to Dr. Mitchell's *literal* infringement opinions). Moderna correctly pointed out in response that Plaintiffs' new and baseless fraud theory was "premised on a single email between Moderna and USG about the '069 Patent, which Plaintiffs dropped from this case after their own infringement testing showed *0% of doses* of the initial version of Moderna's vaccine infringed." D.I. 597 (Moderna's Reply SJ Br.) at 7. Having been called out on their misleading assertion, Plaintiffs in sur-reply conceded Moderna was correct and pivoted to *make up an entirely new and untimely basis* for their fraud theory, this time relying on Dr. Mitchell's opinions on alleged infringement under the *doctrine of equivalents*.<sup>2</sup> D.I. 610 (Plaintiffs' Sur-Reply SJ Br.) at 4–5 (citing "Ex. 48 (Mitchell) ¶¶ 680, 738," which correspond to Dr. Mitchell's DOE opinions).

The Court did not set up summary judgment cross-motions procedures to be a game of whack-a-mole. But that is precisely what Plaintiffs have attempted in an effort to get this statutory defense before a jury, rather than decided by the court before trial.

**B. Dr. Mitchell's Report Could Not Have Been Authored by Him**

For similar reasons to those set out in Moderna's Motion to Exclude Expert Opinions of Dr. Mitchell Regarding Plaintiffs' Cross-Motion for Summary Judgment (D.I. 595; D.I. 596 at 16–20), the Court should not consider the opinions set forth in Dr. Mitchell's report for purposes of summary judgment on the issue of § 1498. Plaintiffs' reliance on the DOE opinions in Dr.

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<sup>2</sup> To be clear, Moderna and its experts do not agree with the opinions provided under Dr. Mitchell's name regarding DOE, nor are those opinions unrebutted; Moderna's experts submitted their own extensive analysis addressing why Plaintiffs' DOE contentions fail.



Mitchell's report further confirms that Dr. Mitchell's claim to have written his own report is impossible. That section of his report spans 100 pages, has over 160 citations to Moderna-produced documents, and refers to 119 spreadsheet appendices that Dr. Mitchell supposedly reviewed and wrote up in two weeks. In those two weeks, for DOE alone, Dr. Mitchell claims to have reviewed Moderna's technical information submitted to the FDA and compared the similarities and differences between three versions of Moderna's COVID-19 vaccine (including clinical and stability data), came up with his own view of the "hypothetical claims" determining their expanded scope, and applied a function-way-result and insubstantial differences analysis. D.I. 571, Ex. 48 (Mitchell Rpt.) ¶¶ 653–741. Nearly all of the material cited in this section of Dr. Mitchell's report was covered by the protective order<sup>3</sup> and therefore could *only* have been reviewed and used to develop Dr. Mitchell's opinions in the 14 days before the deadline for opening expert reports.

Plaintiffs claim that Dr. Mitchell could have been working on sections of the opening report before the undisputed two-week period in which Dr. Mitchell had access to Moderna confidential information. D.I. 611 (Plaintiffs' MTE Opp.) at 17. However, while Plaintiffs claim that Sections I–VIII of Dr. Mitchell's opening report contain "substantial portions" that do not involve Moderna's confidential information, those sections make up just 15% of the report. D.I. 617-3, Ex. 124 (Mitchell Rpt.) at 2–3 (Table of Contents listing 90 of 615 pages in Sections I–VIII). Dr. Mitchell claims to have written at least 525 pages of his report in that two-week window while working as a professor. D.I. 600-6, Ex. 88 (Mitchell Tr.) at 14:18–15:2, 20:2–21:24. Plaintiffs offer no explanation as to how he completed the report in that time, because such a claim is untenable. Dr. Mitchell's statements otherwise only further compound the prejudice and violation

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<sup>3</sup> Moderna's production documents cited in the report of Dr. Mitchell, the vast majority of which are confidential documents on the technical aspects of Moderna's COVID-19 vaccine, have the bates prefix MRNA-GEN.

of Rule 26, warranting exclusion. *See In re Jackson Nat. Life Ins. Co. Premium Litig.*, 2000 WL 33654070, at \*2 (W.D. Mich. Feb. 8, 2000) (evidence that expert testified untruthfully at deposition concerning authorship was “more than a mere ‘technical violation,’” the court noting that the expert’s untruthful deposition testimony “actually compounded the violation. When confronted with questions about the report’s authorship, Mr. Bieluch gave misleading and evasive answers. It is this conduct by Mr. Bieluch, and plaintiffs’ counsel, in the deposition, reflecting a cavalier or stubborn disregard for the Rules of Civil Procedure and the integrity of the judicial process which, in the Court’s opinion, justifies the sanction imposed. The magistrate judge did not abuse his discretion in ordering Mr. Bieluch’s testimony excluded.”).

Plaintiffs argue that Dr. Mitchell spent 92 hours preparing his opening report and cite their counsel’s billing records. D.I. 611 (Plaintiffs’ MTE Opp.) at 17. Those “records,” D.I. 617-18, Ex. 139, consist of a single line item generated from an accounting system that does not indicate *when* Dr. Mitchell expended the alleged 92 hours of work or provide any narrative as to whether Dr. Mitchell was reviewing public documents, Plaintiffs’ documents, or Moderna’s highly confidential documents, which he was only permitted to access starting November 11, 2024—just 14 days before signing his opening report. Plaintiffs did not produce the actual invoice or offer any evidence of the amount of hours Dr. Mitchell spent reviewing Moderna’s confidential information to draft 500+ pages of his report, instead stating that the 92 hours were accrued between October 16, 2024 and November 25, 2024, without any more granular breakdown (e.g., showing the number of hours spent between November 11 and November 25). D.I. 617 (Lachman Decl.) ¶ 2.

**C. Plaintiffs’ Attempt to Equate Dr. Mitchell with Moderna’s Experts Fails**

While Plaintiffs try to claim that Moderna’s experts are similarly situated (D.I. 611 (Plaintiffs’ MTE Opp.) at 16–17), that is far from correct. Moderna’s experts Dr. Prud’homme and Dr. Anderson both largely opined based on *public* information in their opening reports on

invalidity, and in order to view Plaintiffs’ confidential information, they were disclosed **7 months** before the deadline. Ex. 120 (disclosure email for Drs. Anderson and Prud’homme sent Apr. 19, 2024). And while Plaintiffs point to Mr. Godshalk, his report was just 27 pages long, and he testified that he wrote it. D.I. 617-13, Ex. 134 (Godshalk Tr.) at 12:9–21. Moderna did not inexplicably hunt down a new expert at the last minute—two and a half years into the lawsuit—leaving that expert with just two weeks to review a mountain of evidence and prepare a report over 500 pages in length.<sup>4</sup>

#### **D. Plaintiffs’ DOE Opinions Are Waived**

The DOE opinions are waived for a further reason. While the Court should not consider any of the opinions set forth in Dr. Mitchell’s report for purposes of summary judgment, the Court should also disregard the DOE opinions because they were raised in relation to § 1498 for the first time in Plaintiffs’ SJ Sur-Reply. *See Socket Mobile, Inc. v. Cognex Corp.*, 2017 WL 3575582, at \*5 (D. Del. Aug. 18, 2017); *see also* D. Del. L.R. 7.1.3(c)(2) (“The party filing the opening brief shall not reserve material for the reply brief which should have been included in a full and fair opening brief.”). The Third Circuit “ha[s] consistently held that ‘[a]n issue is waived unless a party raises it in its opening brief, and for those purposes a passing reference to an issue . . . will not suffice to bring that issue before this court.’” *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II)*, 751 F.3d 150, 157 (3d Cir. 2014).

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<sup>4</sup> Of note, this two-week period followed a five-month extension sought by Plaintiffs, which was purportedly needed to incorporate fact discovery into their expert reports. D.I. 404 (Aug. 26, 2024 Hr’g Tr.) at 5–6 (Plaintiffs’ counsel representing to Judge Goldberg that they needed a five month extension in fact discovery to “obtain [additional] fact discovery [on infringement], digest that information, **incorporate it into our expert reports**” for the proposed November 25, 2024 deadline) (emphasis added).

### **III. CONCLUSION**

For the foregoing reasons and the reasons in Moderna's Opening Brief, Moderna respectfully requests that the Court exclude the opinions of Dr. Mitchell for purposes of summary judgment.

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**CERTIFICATE OF SERVICE**

I hereby certify that on September 26, 2025, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on September 26, 2025, upon the following in the manner indicated:

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